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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/996,484 | 11/28/2001 | Yen Choo | 8325-2004 G8-US1 | 2713 |
| 20855 | 7590 | 06/03/2004 | EXAMINER | |
| ROBINS & PASTERNAK 1731 EMBARCADERO ROAD SUITE 230 PALO ALTO, CA 94303 | | | SULLIVAN, DANIEL M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/996,484 | Applicant(s) CHOO ET AL. | |
| | Examiner Daniel M Sullivan | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,21-35 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-18,21-33,35 and 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/3/03;4/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 28 November 2001, which claims benefit under 35 U.S.C. §119(a)-(d) of international application PCT/GB00/02080 filed 30 May 2000, UK application 9912635.1 filed 28 May 1999 and UK application 0001582.6 filed 24 January 2000. The preliminary amendments filed 28 November 2001, 8 April 2002, 13 May 2003 and 16 April 2004 have been entered. Claims 1-47 were originally filed. Claims 19, 20, 36 and 37 were canceled and claims 3, 4, 6-18, 21, 23, 27, 29-32, 34, 35, 41, 42 and 44-47 were amended in the preliminary amendment filed 28 November 2001. Claim 34 was amended in the preliminary amendment filed 16 April 2004. Claims 1-18, 21-35 and 38-47 are pending.

Election/Restrictions

Applicant's election without traverse of Group III (claim 34) in the Paper filed 16 April 2004 is acknowledged. In the "Remarks" of the 16 April Paper, Applicant reserves the right to rejoinder of the process claims of Group I according to the provisions of MPEP § 821.04. However, Applicant is reminded that process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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As indicated in the restriction requirement mailed 18 March 2004, the process of Group I as claimed can be used to make either of the patentably distinct products of Inventions II and III. If Applicant wishes to reserve the right to rejoinder of the process claims, the claims must be amended, during prosecution of the application, such that they are commensurate in scope with the claimed product.

Claims 1-18, 21-33, 35 and 38-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in the United Kingdom on 28 May 1999 and 24 January 2000. It is noted, however, that applicant has not filed a certified copy of the UK applications as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The references cited on the Information Disclosure Statement filed 16 April 2004 were already cited in the Information Disclosure Statement filed 3 November 2003. The references have been considered as indicated on the 3 November PTO/SB/08A. Duplicate references cited on the 16 April PTO/SB/08A have been lined through.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 34 is rejected under 35 U.S.C. 102(a) as being anticipated by Uchida *et al.* (1999)

J. Mol. Endocrinol. 23 : 347-353.

Claim construction

The instant claim 34 is directed to a switching system comprising a switch comprising: (i) a first component comprising a first polypeptide and (ii) a second component comprising a second polypeptide in which the first polypeptide binds to the second polypeptide in a manner modulatable by a ligand and (iii) a third component comprising the ligand. The claim further recites method steps by which the claimed switching system might be “selected”; however, as *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” Thus, absent evidence to the contrary, the switching system of the instant

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claim 34 reads on any system comprising elements (i), (ii) and (iii) regardless of how that system was selected.

Uchida *et al.* teaches a switching system comprising a first and second polypeptide that bind to one another in a manner modulatable by a ligand, and a ligand. Specifically, Uchida *et al.* teaches that binding of human growth hormone with its receptor induces dimerization of the receptor proteins resulting in an active dimeric receptor-ligand complex (see especially Figure 5 and the caption thereto). The switching system of Uchida *et al.* is the same as the switching system of the instant claim 34.

Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by any one of Nicola (1995) *Ann N Y Acad Sci.* 766:253-262, Carpenter *et al.* (1995) *Ann N Y Acad Sci.* 766:44-51, McEwan *et al.* (1996) *BioEssays* 19 :153-160 or Alberts *et al.* "Mechanisms of Transduction by Cell-Surface Receptor Proteins" in Molecular Biology of the Cell: second edition, pp. 693-708, Garland Publishing, Inc. NY, 1989.

Nicola teaches that binding of a wide variety of cytokines to their receptors produces a multimeric receptor-ligand complex analogous to the hGH receptor complex described by Uchida *et al.*, wherein the proteins that make up the complexes can be the same or different (see especially the paragraph bridging pages 254-255, Figure 1 and the caption thereto). The switching systems described by Nicola anticipate the switching system of the instant claim 34.

Carpenter *et al.* teaches, "[a]t least seven SH2-containing molecules have been detected to associate with the activated EGF receptor" (page 45, lines 10-11). Thus, Carpenter *et al.*

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describes a switching system comprising a first and second polypeptide (*i.e.*, an EGF receptor and an SH-2 containing protein) that bind to one another in a manner modulatable by a ligand (*i.e.*, EGF), and the ligand.

McEwan *et al.* teaches that the glucocorticoid receptor and members of the steroid-thyroid hormone receptor superfamily are known in the art to interact with a wide variety of proteins in a ligand dependent manner (see especially Table 1 and the section entitled “Proteins interacting with the GR”, particularly the paragraph bridging pages 156-157). Thus, McEwan describes several art-recognized switching systems comprising a first and second polypeptide that bind to one another in a manner modulatable by a ligand, and a ligand, which anticipate the switching system of the instant claim 34.

Alberts *et al.* teaches that G-protein coupled receptors, which comprise a very large superfamily of structurally and functionally related proteins, interact with G-proteins upon ligand binding (see especially Figure 12-17 and the caption thereto). Thus, Alberts *et al.* describes a switching system comprising a first and second polypeptide (*i.e.*, G-protein coupled receptor and G-protein) that bind to one another in a manner modulatable by a ligand, and a ligand. The switching system described by Alberts *et al.* anticipates the switching system of the instant claim 34.

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Menzel *et al.* US Patent No. 6,265,174 (effective filing date 3 November 1997)

Menzel *et al.* discloses a switching system comprising a first and second polypeptide that bind to one another in a manner modulatable by a ligand, wherein the first and second

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polypeptides are CadC-EPO receptor or CadC-insulin receptor fusion proteins, and a ligand (*i.e.*, EPO or insulin; see especially the section entitled "13.2 Ligand-induced specific modulation of CadC-fusion polypeptide activity in CadC-based autocrine system beginning in column 49). The switching system described by Menzel *et al.* is the same as the switching system of the instant claim 34.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS


DAVID GUZO
PRIMARY EXAMINER